SYNOPSIS

NAME OF SPONSOR/COMPANY: Ortho Biotech Clinical Affairs, LLC. NAME OF FINISHED PRODUCT: Procrit NAME OF ACTIVE INGREDIENT(S): Epoetin Alfa	INDIVIDUAL STUDY TABLE REFERRING TO PART OF THE DOSSIER N/A	(FOR NATIONAL AUTHORITY USE ONLY) N/A
Protocol No.: PR03-19-057 **Title of Study:** A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of Procrit® (Epoetin alfa) on Short-Term Outcomes in Orthopedic Subjects Undergoing Primary Unilateral Knee Arthroplasty		
Study Initiation/Completion Dates: 2 March 2005 (FPI) / 6 October 2005 (LPO)		**Phase of development: II**
Objectives: To compare the effect of perioperative administration of Procrit® to that of preoperative autologous donation on post-operative rehabilitation outcomes in subjects undergoing primary unilateral knee arthroplasty.		
Methodology: The ANCOVA method will be used to analyze the primary endpoint with baseline (preoperative day-21) FIM score as a covariate.		
Criteria for Evaluation: The change in composite FIM score from entry into an inpatient rehabilitation facility to discharge (i.e., discharge from the inpatient rehabilitation facility) or post-operative day +28 (if not discharged by post-operative day +28) divided by the length of stay (LOS) in the inpatient rehabilitation facility, denoted as ΔFIM/LOS, or "rate of functional recovery".		
SUMMARY - CONCLUSIONS EFFICACY RESULTS: This study was discontinued due to poor enrollment. Data analysis was not performed because only 6 subjects were enrolled. SAFETY RESULTS: No Serious Adverse Events were reported. No significant non-serious adverse events were reported.		

SYNOPSIS (CONTINUED)

NAME OF SPONSOR/COMPANY: OBCA LLC NAME OF FINISHED PRODUCT: Procrit NAME OF ACTIVE INGREDIENT(S): Epoetin Alfa	INDIVIDUAL STUDY TABLE REFERRING TO PART OF THE DOSSIER Volume: Page:	(FOR NATIONAL AUTHORITY USE ONLY)

CONCLUSION:

No conclusions were drawn from this study due to small sample size of the study population.

Date of the report: 05 April 2006

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